

SUBJECT:	Fermilab Corrective & Preventive Action Plan – Form 1	NUMBER:	1004.1001 FORM 1
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001
APPROVED BY:	Head, Office of Quality and Best Practices	EFFECTIVE:	03/31/10

CAP INITIATION – CORRECTIVE ACTION REQUEST

This section to be completed by the person requesting corrective / preventive action

Requestor Name: John Martzel

Organization: OQBP

Phone: 5061

Nonconformity/Opportunity To Be Addressed:

The TD Quality Management Program Document (TD-2010) states: "...ensure that all issued documents contain the most current information." The following instances are examples where the assessment team observed processes in use that did not contain the most current information:

- Procedures 333500, 333901, and 333902 found on equipment contained hand written changes. These hand-written changes have existed for an extended period of time without the official copy being updated. The TD Quality Management Program Document (TD-2010) section 4.4 paragraph 3 states: "...authorized personnel may make hand-written changes to controlled documents as a temporary change only. The altered document should go through revision control as soon as is practical."
- The hard copy procedures 333906 and 333916 located on the corresponding equipment were an out of date revision.
- The Cable Making Machine Operation Guide is not controlled as it has no identification number, no date, and has not been approved.
- Procedure TID-N-76 is no longer accurate because the clean room configuration has been updated.
- Procedure TID-N-106 needs to be updated to reflect the new McQuay chiller that is used.
- There was 1 instance of a person who did not know how to find the controlled procedure documents online. (He had an obsolete hard copy of his procedure.)

Unique Tracking Number: DS-YYYYMMDD-xx: OQ-20100623-02
(DS=Div or Sec, YYYYMMDD-xx = Date Opened, x=1, 2, ...n)

*** Other Tracking Number:** ESHTRK #81942
(Ex: ESHTRAK #, DMR # etc)

Responsible Person: Jamie Blowers

Organization: TD

Phone: 2800

Validation Required for Closure: Requestor: X Responsible Person: X None:

***Comments:**

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CAP DEVELOPMENT CAP Version (increment by 1 with each change) 001

This section to be completed by the Responsible Person

Describe the Actual Nonconformity/Opportunity, and What Caused it (Root Cause):

Similarly to the other CAP related to this assessment (TD-20100623-01) this CAP has to do with how we manage changes to our documented procedures. In this case (with one exception, i.e. the cabling machine procedure) changes were known about but were not reflected in the official controlled documents. Just as in the other CAP, the root cause is lack of communication regarding our expectations.

Remedial/Compensatory, Corrective, and/or Preventive, actions being taken and

(where applicable) Lessons Learned: Corrective actions: all the procedures listed above will be revised to match the actual work practices, and the Cabling Machine Operating Guideline document will be made into an official operating procedure. Preventive actions: the T&I department is communicating with their supervisors and employees of the importance of working to documented procedures, and that changes which are accepted by the responsible authorities need to be incorporated into the written procedures in a timely manner. The Process Engineering (the group within QMD responsible for managing the operating procedures for most of TD) will ensure that revised operating procedures are placed on the appropriate equipment whenever procedures are revised (replacing the obsolete versions), and they will schedule time with area supervisors on a regular basis to ask about changes to operating procedures that should be incorporated into the official documents.

Planned start date (YYYYMMDD): 2010-07-01

Key milestones and Dates:

Estimated date for completion (YYYYMMDD): 2010-12-31

Who will complete the work T&I: Ruben Carcagno; **QMD:** Jamie Blowers
x3915; x2800

Phone:

Who will perform verification and/or validation John Martzel

Phone: 5061

***Comments:**

CAP APPROVAL,

This section to be completed and signed by person identified below

**** Approval Manager:**



Date: 2011-03-25
(YYYYMMDD)

***Comments:**

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CAP CLOSURE

This section to be completed and signed by persons identified below

Description of actions taken to implement (if different than plan):

****Implemented By:** Jane Blee **Date:** 09-Jan-2011
(YYYYMMDD)

****^Verified By:** John Marty **Date:** 09-June-2011
(YYYYMMDD)

***Comments:** _____

**** Acceptance Requestor:** John Marty **Date:** 09-June-2011
(YYYYMMDD)

***Comments:** _____

See Fermilab Corrective Action Plan Guide to Form 1 for a completed example